

REMARKS

The present communication responds to the Office Action dated August 13, 2004. In that Office Action, the Examiner rejected claims 40-45 as being unpatentable over Brinkerhoff et al. or Cuschieri et al. in view of Crane et al., and Coleman et al.. This rejection is respectfully traversed in view of the above amendments and because none of the references disclose permanently or semi-permanently implanting a port body.

Rejection under 35 U.S.C. § 103

Claims 40-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinkerhoff et al or Cushieri et al in view of Crane et al. and Coleman et al. This rejection is traversed at least for the following reasons.

Brinkerhoff et al.

The Brinkerhoff reference discloses an endoscopic surgical sealing device. The device is partially inserted into an abdominal opening in a deflated state, and then inflated to provide a seal for obstructing the passage of gas from the abdominal cavity during endoscopic surgery. The Examiner cites Brinkerhoff for it's teaching of Figure 5. The Examiner asserts that Figure 5 of Brinkerhoff discloses a port body having a selective accessible exposed portion external to the body and, further, a self-closing diaphragm. The Examiner further asserts that Figure 5 of Brinkerhoff shows a tube inherently capable of infusing or aspirating fluids to and from the body.

The applicants respectfully disagree with the Examiner's interpretation of the Brinkerhoff reference. Brinkerhoff does not teach a self-closing diaphragm. Nor does Brinkerhoff teach passing a medicament through a feed tube or aspirating body fluids in an aspiration tube. Brinkerhoff describes the sealing device shown in Figure 5 as:

an inflatable sealing device used in a trocar instrument to provide a seal around an endoscopic instrument inserted through it and thereby maintain pressure in the abdominal cavity. *Brinkerhoff, Column 4, lines 9-13.*

Brinkerhoff describes the use of the inflatable sealing device of Figure 5 in a trocar during a laparoscopic procedure to provide a seal around an endoscopic instrument:

The function of the sealing device in this embodiment is illustrated in FIGS. 5 and 6. In the laparoscopic procedure, the trocar 41 is inserted through the abdominal wall 47 into the abdominal cavity 48 to allow instruments to pass through the abdominal wall 47 to accomplish the procedure while the abdominal cavity 48 is under gas pressure. The trocar 41 is naturally sealed at the abdominal wall 47 by the elastic nature of the tissue in the abdominal wall 47. *Brinkerhoff, Column 5, lines 57-65.*

It appears that the Examiner is citing the trocar shown in Figure 5 as "a port body having a selective accessible exposed portion external to the body" and as "a tube inherently capable of infusing or aspirating fluids to and from the body." The Brinkerhoff device does not include a trocar but may be used with a trocar. A trocar is a sharp-pointed surgical instrument, used with a cannula to puncture a body cavity. Brinkerhoff describes:

The laparoscopic technique uses smaller puncture openings in the abdominal wall as described. These openings are usually made with a puncture device called a trocar. The trocar point and attached shaft are usually contained in a hollow circular tube which remains in the abdominal wall after puncture and through which other instrument shafts are passed to be used in the operating procedure. *Brinkerhoff, Column 1, lines 57-64.*

Thus, with regards to the trocar, Brinkerhoff merely teaches using a trocar as trocars are commonly used. Brinkerhoff does not teach an aspiration tube or a feed tube depending from the port body, as required by claims 40 and 70. Further, there is no teaching by Brinkerhoff of infusing or aspirating fluids to and from the body. In contrast, Brinkerhoff specifically teaches using the trocar as an access for endoscopic instruments.

Further, Brinkerhoff teaches using a trocar and the sealing device during surgery. By its very nature, surgery is temporary. Brinkerhoff does not teach permanently or semi-permanently implanting a port body into a body.

Brinkerhoff does not teach a self-closing diaphragm. To provide a seal, the inflatable sealing device 40 includes a central lumen 46 that may be closed by inflating an inflatable toroidal section 42 using an inflation and deflation means 44:

The trocar opening 49 into the body cavity 48 is sealed against leakage of gas by the closing of the central lumen 46 of the sealing device 40 when the sealing device 40 is

inflated as illustrated in FIG. 5. The central lumen 46 of the sealing device 40 is easily opened by inserting an endoscopic instrument 50. The gas sealing is accomplished between the endoscope instrument 50 and the trocar 41 as shown in FIG. 6 by inflation pressure inside the toroidal section 42 of the sealing device 40 forcing the central lumen 46 to close tightly around the movable endoscopic instrument 50. *Brinkerhoff, Column 5, line 65 – Column 6, line 2.*

Although the Examiner asserts that Brinkerhoff teaches a self-closing diaphragm, Brinkerhoff explains that a trocar is naturally sealed by the elastic nature of the tissue in the abdominal wall. The elastic nature of tissue in the abdominal wall in sealing a trocar does not provide a self-closing diaphragm of a port body. Brinkerhoff also teaches providing a seal by inflating a toroidal section of a sealing device. However, a section of a device that requires inflation for providing a seal does not provide a self-closing diaphragm of a port body.

Claims 40 and 70 require permanently or semi-permanently implanting a port body into a body, an aspiration tube depending from the port body and a fluid tube depending from the port body, passing a medicament into a feed tube, and aspirating body fluids in an aspiration tube wherein the body fluids are tested. Brinkerhoff does not teach any of these things.

Cuschieri et al.

The Cuschieri reference discloses an extracorporeal pneumoperitoneum access bubble. The Examiner cites Cuschieri for its teaching of Figure 5. The Examiner asserts that Figure 5 of Cuschieri discloses a port body having a selective accessible exposed portion external to the body and, further, a self-closing diaphragm.

The applicants respectfully disagree with the Examiner's interpretation of the Cuschieri reference. Cuschieri explains the use of the access bubble device as being used to provide access to organs during laparoscopic procedures:

The medical device according to the present invention provides an extension of the pneumoperitoneum during laparoscopic procedures which allows improved access to the organ or organs being worked upon. The device also allows the simultaneous, multiple entry and withdrawal of a wide range of surgical instruments through a single incision in the abdominal wall, and may hence reduce the overall number of puncture sites needed for the procedure. The device can include means for allowing access of the surgeon's hand or hands to the pneumoperitoneum and the device can be of a transparent material

which allows clear observation during the surgical procedure. *Cuschieri, Column 2, lines 52-63.*

Thus the Cuschieri device is used during a surgical procedure. By its very nature, surgery is temporary. Cuschieri does not teach permanently or semi-permanently implanting a port body into a body.

The Cuschieri device includes an enclosure and a deploying means which can be inserted into a trocar puncture site.

The deploying means then expands beneath the inner surface of the abdominal wall. By applying a gentle lifting force on the enclosure, the deploying means forms a seal with the abdominal wall allowing insufflation gas in the abdominal cavity to inflate the enclosure into a "balloon" shape. Once inflated, the internal gas pressure in the abdominal cavity maintains the device in a stable shape. The device includes one or more access openings which allow access to the interior of the enclosure, and hence the abdominal cavity. *Cuschieri, Column 3, lines 16-26.*

The deploying means preferably returns to its original shape after being elastically deformed by an external force. *Cuschieri, Column 4, lines 7-8.*

The Examiner did not state what portion of Cuschieri could be interpreted as a port body having a selective accessible exposed portion external to the body. However, even if one were to interpret the access bubble in its entirety as a port implanted in the body, the access bubble does not have an aspiration tube or a feed tube depending therefrom, as required by claims 40 and 70. Indeed, the deploying means of the Cuschieri device is not configured for allowing tubes to depend therefrom, the deploying means instead expanding beneath the inner surface of the abdominal wall to form a seal.

Claims 40 and 70 require permanently or semi-permanently implanting a port body into a body, an aspiration tube depending from the port body and a fluid tube depending from the port body, passing a medicament into the feed tube, and aspirating body fluids in the aspiration tube wherein the body fluids are tested. Cuschieri does not teach any of these things.

Crane et al.

The Crane reference discloses a cranial bolt. The Examiner cites Crane for its teaching of Figure 3. The Examiner states that Crane discloses a bolt that can be used to install single or

multi-lumen catheters, sensors, drainage or sampling tubes into various parts of the brain. The Examiner argues that the guide tubes (21, 22) can be used to infuse drugs, aspirate or drain a selected site, and even introduce a sensor. The Examiner asserts that, for a person of ordinary skill in the art, modifying the ports disclosed by Brinkerhoff et al. or Cuschieri et al. with guide tubes capable of infusing fluids, draining fluids or sensing body fluids would have been considered obvious design choices.

The applicants respectfully disagree with the Examiner's assertions. Crane teaches a cranial bolt for connecting one or more elongate, flexible members such as catheters with the interior of the skull. Crane explains that cranial bolts are temporary:

Cranial bolts are frequently used for temporarily securing a catheter to the skull, the catheter being used for monitoring intercranial pressure in the intensive care of patients who have suffered head injuries. *Crane, Column 1, lines 11-14.*

Thus, Crane does not teach permanently or semi-permanently implanting a port body into a body.

While Crane discloses that the bolt may be used to introduce various items to the brain, Crane does not disclose how this can be done without the use of the bolt. Indeed, the bolt of the invention is specifically intended for introducing such items:

The bolt in accordance with the invention can be used to install single or multi-lumen catheters, sensors, or drainage or sampling tubes into various parts of the brain, including the ventricles, sub-dural, epidural or parenchymal areas of the brain. Sampling tubes may include microdialysis catheters in which a saline solution is passed down one lumen and samples of chemicals in the brain are extracted through a second lumen via a membrane, and the extracted fluid analysed. *Crane, Column 4, lines 10-18.*

Given that the specific teaching of Crane goes to how to introduce such items, it is unclear how Crane can be interpreted for making obvious introducing such items without using the bolt of Crane. Further, as stated above in regards to Cuschieri, there is no teaching in Cuschieri as to how an aspiration tube or a feed tube could depend from the access bubble taught therein. Crane does not provide any further guidance on this issue. Similarly, Brinkerhoff teaches a trocar used in the conventional manner of a trocar. There is no teaching in Brinkerhoff or Crane as to how an aspiration tube or a feed tube could depend therefrom.

Claims 40 and 70 require permanently or semi-permanently implanting a port body into a body, an aspiration tube depending from the port body and a fluid tube depending from the port body, passing a medicament into a feed tube, and aspirating body fluids in an aspiration tube wherein the body fluids are tested. The teachings of Brinkerhoff or Cuschieri, even when combined with the teachings of Crane, do not teach these things.

Coleman et al.

The Coleman reference discloses an apparatus and method for in-vivo measurements of chemical concentrations. The Examiner cites Coleman for its teaching of Figures 2a-2c and 3. The Examiner asserts that the figures of Coleman demonstrate the conventionality of sensing and analyzing body fluids within an aspiration tube. The Examiner specifically notes that a plunger is used to aspirate fluids so that the fluids can establish contact with a sensor. The Examiner asserts that, based on the teachings of Coleman et al., the analysis of body fluids within an aspiration tube or outside the port body would have been considered by a person of ordinary skill in the art an obvious design choice.

The applicants respectfully disagree with the Examiner's assertions. Coleman teaches a measuring apparatus for making in-vivo determinations of the concentrations of light absorbing chemicals in biological fluids of a body. *Coleman, Column 3, lines 33-35*. As with most testing devices, the testing device is not implanted in the body and trauma is caused to the patient each time the fluids are tested:

In operation, the probe 12 is inserted into a body so that the needle point 19 is positioned in the region of biological fluids to be tested. A suction is then placed on the aspiration port 24 and the biological fluids are drawn into the sample cavity 26. *Coleman, Column 4, line 67 – Column 5, line 3*.

As stated at page 2 of the present application, "another piercing procedure involves piercing the skin with needles for introducing and/or retrieving a sensor at a test point in the body." This is a problem specifically solved by the present invention. As stated at page 4 of the present application:

It is an advantage of the present invention that permanent or semi-permanent implanted access means may be used to allow access to body fluids for analysis over an extended

period of time and/or to allow for repeated sampling or analysis of body fluids, while sparing a patient the discomfort of repeated piercings.

Coleman teaches testing device requiring repeated piercings of a patient for each sampling or analysis of body fluids.

Claims 40 and 70 require permanently or semi-permanently implanting a port body into a body, an aspiration tube depending from the port body and a fluid tube depending from the port body, passing a medicament into a feed tube, and aspirating body fluids in an aspiration tube wherein the body fluids are tested. The teachings of Brinkerhoff or Cuschieri, even when combined with the teachings of Coleman, do not teach these things.

Brain

The Brain reference discloses a laryngeal mask airway with concentric drainage of oesophagus discharge. The Examiner asserts that Brain teaches the capability of analyzing fluids after the step of aspiration from a tube. Specifically, the Examiner refers to Brain, Column 6, lines 29-33.. The Examiner asserts that, based on the teachings of Brain, the analysis of body fluids within an aspiration tube or outside the port body would have been considered by a person of ordinary skill in the art an obvious design choice.

The applicants respectfully disagree with the Examiner's assertions. Brain teaches a laryngeal mask airway which is fitted with an evacuation or drainage tube which passes through the back of the mask and terminated concentrically within an inflatable-cuff formation at the distal end of the mask. Specifically, the embodiment shown in Figure 6 (referenced at Column 6, lines 29-33) shows:

a mask 30, having a connection to an airway tube 31, as in FIGS. 1 to 5, also has a relatively stiff body 32, peripherally surrounded by a soft flexible ring 33 that is selectively inflated or deflated via an externally accessible inflation tube 34. Provision for evacuation or drainage of gastric products involves two like tubes 35, 36 which conform to and are carried by airway tube 31. *Brain, Column 6, lines 11-18.*

As noted by the Examiner, Brain then teaches that products may be collected from tube 36 for analysis:

Alternatively, a steady flow of fluid may be drawn from tube 36, having been thereby induced to flow into the external end of tube 35 (as suggested by arrows 35', 36' in FIG. 6), thereby at the same time aspirating, for external collection, analysis and/or discard, such gastric products as may have entered the single central passage 37. *Brain, Column 6, lines 29-35.*

Thus, Brain does show collecting samples for analysis. As stated at page 2 of the present application, "Virtually any intercellular fluid may be examined in many different ways and for different characteristics using a selected 'test strip' after such a fluid has been obtained." While Brain shows a method for collecting samples, Brain does not teach the present invention.

Claims 40 and 70 require permanently or semi-permanently implanting a port body into a body, an aspiration tube depending from the port body and a fluid tube depending from the port body, passing a medicament into a feed tube, and aspirating body fluids in an aspiration tube wherein the body fluids are tested. The teachings of Brinkerhoff or Cuschieri, even when combined with the teachings of Brain, do not teach these things.

Conclusion

By the above amendment claims 28-39 have been canceled. Remaining claims 40-45 and 56-81 are patentable over the cited prior art at least for the reasons set forth above. Thus, it is respectfully requested that the rejection of claims 40-45 and 56-81 be withdrawn.

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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